

Claims:

1. A controlled-release formulation for oral administration containing a cGMP PDE-5 inhibitor; provided that the formulation does not consist essentially of sildenafil, low molecular weight polyethylene oxide, hydroxypropylmethyl cellulose, tableting excipients, and optionally one or more enteric polymers.
2. A formulation as claimed in claim 1, which is a sustained-release formulation.
3. A formulation as claimed in claim 1 ~~or claim 2~~, wherein up to 75% by weight of the cGMP PDE-5 inhibitor is released from the formulation into the gastrointestinal tract after a period of time in the range 1-24 hours following administration.
4. A formulation as claimed in claim 2 ~~or claim 3~~, wherein the cGMP PDE-5 inhibitor is embedded in a matrix from which it is released by diffusion or erosion.
5. A formulation as claimed in ~~any one of claims 2 to 4~~ ^{claim 2}, wherein the cGMP PDE-5 inhibitor is present in a core which is coated with a release rate-controlling membrane.
6. A formulation as claimed in ~~any one of claims 2 to 4~~ ^{claim 2}, which comprises a core containing the cGMP PDE-5 inhibitor and an outer coating impermeable to the cGMP PDE-5 inhibitor, the outer coating having an aperture for release of the cGMP PDE-5 inhibitor.
7. A formulation as claimed in ~~any one of the preceding claims~~ ^{claim 1}, wherein the cGMP PDE-5 inhibitor is sildenafil, or a pharmaceutically acceptable salt thereof.
8. A formulation as claimed in claim 7, wherein the cGMP PDE-5 inhibitor is sildenafil citrate.
9. A formulation as claimed in claim 4, which also contains hydroxypropylmethyl cellulose.
10. A formulation as claimed in claim 4 ~~or claim 9~~, which also contains a buffering agent.
11. A formulation as claimed in claim 9 ~~or claim 10~~, wherein the hydroxypropylmethyl cellulose has a number average molecular weight in the range 80,000-250,000.
12. A formulation as claimed in ~~any one of claims 9 to 11~~ ^{claim 9}, wherein the hydroxypropylmethyl cellulose has a degree of methyl substitution in the range 19-30%.
13. A formulation as claimed in ~~any one of claims 9 to 12~~ ^{claim 9}, wherein the hydroxypropylmethyl cellulose has a degree of hydroxy substitution in the range 7-12%.
14. A formulation as claimed in ~~any one of claims 9 to 13~~ ^{claim 9}, wherein the hydroxypropylmethyl cellulose makes up 10-50% by weight of the formulation.

15. A formulation as claimed in claim 5, wherein a multiplicity of coated cores is present.

16. A formulation as claimed in claim 15, wherein the core also includes a buffering agent.

5 17. A formulation as claimed in claim 5, ~~claim 15 or claim 16~~, wherein the release rate-controlling membrane comprises an ammonio methacrylate copolymer and a plasticizer.

18. A formulation as claimed in ~~any one of the preceding claims~~ ^{claim 1}, which is provided with a cosmetic coating.

19. A formulation as claimed in ~~any one of the preceding claims~~ ^{claim 1}, wherein the cGMP
10 PDE-5 inhibitor makes up 5-50% by weight of the formulation.

20. A formulation as claimed in ~~any one of the preceding claims~~ ^{claim 1}, characterized in that the rate at which the cGMP PDE-5 inhibitor is released therefrom is substantially independent of the pH of the surroundings.

21. A process for the production of a formulation as defined in claim 4, ~~claim 5 or claim 6~~, which includes the steps of:

- (a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into tablets;
- (b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the core with a release rate-controlling membrane; or
- (c) forming a core containing the cGMP PDE-5 inhibitor and then coating the core
20 with a coating impermeable to the cGMP PDE-5 inhibitor;
respectively.

22. Use of a cGMP PDE-5 inhibitor in the manufacture of a formulation for the treatment or prevention of sexual dysfunction; characterized in that, following administration, the formulation releases the inhibitor over or after a sustained period of
25 time.

23. The use of claim 22, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.

24. A method of treating or preventing sexual dysfunction, which comprises administering a controlled-release formulation, as defined in claim 1, but without proviso,
30 to a mammal in need of such treatment or prevention.

25. The method of claim 24, characterized in that, following administration, the mammal's sexual function is substantially improved for or after a sustained period of time.

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26. A method of improving sexual function in a mammal, which comprises administering a controlled-release formulation, as defined in claim 1, but without proviso. to the mammal.

27. The method of claim 26, characterized in that, following administration, the
5 mammal's sexual function is substantially improved for or after a sustained period of time.

28. A method of increasing the probability of a nocturnal erection in a male mammal, which comprises administering a controlled-release formulation, as defined in claim 1, but without proviso, to the male mammal.

29. A dual release formulation for oral administration having a first portion comprising
10 a controlled-release formulation as defined in claim 1, but without proviso, and a second portion comprising a cGMP PDE-5 inhibitor in immediate release form.

30. Products containing a controlled-release formulation as defined in claim 1, but without proviso, and a cGMP PDE-5 inhibitor in immediate release form, as a combined preparation for simultaneous, separate or sequential use in the treatment or prevention of
15 sexual dysfunction.

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